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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,175	05/24/2001	Thomas Tobin	434-226	3002

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EXAMINER
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COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 08/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/865,175	Applicant(s) TOBIN, THOMAS	
	Examiner Rebecca Cook	Art Unit 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☐ Responsive to communication(s) filed on 26 June 2002 and 01 August 2002.

2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 20-48 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 20-48 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All   b) ☐ Some \*   c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> .	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____
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In view of the cancellation of claims 1-19, the earlier objections and rejections to them under 35 U.S.C. 112, paragraphs two and 103(a) are moot.

In view of the amendment to claim 22, the rejection under 35 U.S.C. 112, paragraph two is withdrawn.

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "or pharmaceutically acceptable derivatives" renders the claim confusing, since the antecedent basis in claim 32~~6~~ is to "a" guanidine derivative. Amending the claim to recite "a pharmaceutically acceptable derivative" will overcome this rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,635,204 (abstract, column 1, among others).

'204 discloses a method of inducing sedation and analgesia using the instant guanidine derivative. It further discloses a method of reversing the analgesia and sedation using the instant .alpha.adrenergic antagonist. The instant claims differ over

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the reference in reciting that the subject is a standing equine animal, and reciting specific routes of administration, subjects and dosages. However, once a method of use is known it is within the scope of the artisan to determine optimum routes of administration, subjects and dosages. Furthermore, no unobviousness is seen in reciting "a standing equine animal" since claim 1 recites "mammal" and <sup>the</sup> specification does not exclude an equine subject.

Claims 20-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over 4,060,640, alone or in view of 5,635,204.

4,060,640 (columns 1-2, claims) disclose a method of induce sedation in mammals using the instant guanidine derivatives. The instant claims differ over the reference in reciting that the subject is a standing equine animal, and reciting specific routes of administration, subjects and dosages. Claims 29 and 42 recite reversing the analgesia and sedation using an instant .alpha.adrenergic antagonist. However, 5,635,204 discloses a method of reversing the analgesia and sedation using the instant .alpha.adrenergic antagonist. Moreover, once a method of use is known it is within the scope of the artisan to determine optimum routes of administration, subjects and dosages. Furthermore, no unobviousness is seen in reciting "a standing equine animal" since claim 1 recites "mammal" and specification does not exclude an equine subject.

In view of the "consisting essentially" language amending claim 20 the earlier rejection of claims 20-35 under 35 U.S.C. 103(a) over 5,635,204 is withdrawn

It is noted that Tables 1-3 contain graphs that should be deleted from the specification and resubmitted as drawings. A section titled "Brief Description of the Drawings" should be added to the specification. See MPEP 608.01 citing 37 CFR 1.58 "Chemical and mathematical formulae and tables" which recites that drawings may not be included in the specification.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday from 5:30 am to 4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
REBECCA COOK  
PRIMARY EXAMINER  
GROUP 1200/6 r4

August 14, 2002